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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784

5514 7590 08/08/2006

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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/749,728

Applicant(s)

UMEZAWA ET AL

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-19,21-28,38,39,41,43,44,47-63 and 78-91 is/are pending in the application.
4a) Of the above claim(s) 47-63 and 78-91 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,6-19,21-28,38,39,41,43 and 44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152).
6) ☐ Other: _____.

DETAILED ACTION

This application filed December 28, 2000, claims benefit to provisional application 60/244,594, filed November 1, 2000; which is a divisional of PCT/JP00/01148, filed February 28, 2000, both of which claim benefit to foreign application 11-372826, filed December 28, 1999 in Japan.

Applicants amendment filed May 16, 2006 has been received and entered. Claims 2-5, 20, 29-37, 40, 42, 45, 46 and 64-77 have been cancelled. Claims 1, 6, 9-19, 21-28, 38, 39, 41, 43, 44, 47-50, 52, 61, 78-86, 88-91 have been amended. Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending.

Examiner comment

For the sake of clarity of the record, Applicants indicated that support for the amendment to claim 1 could be found on page 24, lines 19-23. Review of the specification for support of the use of adult stem cells which are CD117 and CD140 positive cells is found on page 25, lines 19-23.

Priority

The original oath/declaration filed December 27, 2000 indicated a claim of priority to PCT/JP00/01148 was made under 35 USC 365(a). The earliest effective filing date in the US was of 60/244,494, filed November 1, 2000. Accordingly, both PCT/JP00/01148, filed February 28, 2000, and foreign application 11-372826, filed December 28, 1999 in Japan were considered

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under 365(a) relative to the earliest effective filing date, i.e. November 1, 2000 of '594. Foreign application 11-372826, filed December 28, 1999 accorded protection against 102(a) type rejections as of its effective filing date.

The application data sheet filed December 28, 2000 indicated a claim of foreign priority to foreign application 11-372826, filed December 28, 1999, but failed to indicate any priority claim to PCT/JP00/01148.

Also note that the claim for priority made in the paper filed August 8, 2003 (providing the priority documents) was under 35 USC 119.

At issue is that the new oath now indicates a claim of priority to PCT/JP00/01148 as a divisional under 36(c), effectively requesting the US effective filing date be February 28, 2000, making the 102(b) date February 28, 1999.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 365(c) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Additionally, it is noted that neither the PCT application nor its translation have been provided to access the claim to priority. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

The disclosure of the prior-filed application, Application No. PCT/JP00/01148, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 365(c), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time

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period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

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Accordingly, the earliest effective US filing date is that of US provisional application 60/244,594, filed November 1, 2000. The claim of benefit to PCT/JP00/01148, filed February 28, 2000, and foreign application 11-372826, filed December 28, 1999 in Japan, are considered under 35 USC 365 (b).

Election/Restriction

Claims 1, 6-19, 21-28, 38, 39, 41, 43, 44, 47-63, 78-91 are pending. Claims 47-63 and 78-91 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 are currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 16, 2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention. Specifically, the amendment to the claim to indicate “An isolate cell”...”comprising” is confusing and unclear to what is encompassed by the claim. FERM BP-7043 is only a single cell line, not multiple cell lines, and it is unclear to what the open claim language refers to be comprised by this deposit. The claim is indefinite because the metes and bounds of the claim can not be determined given the instant language of the claim.

More clearly indicating a claim to the deposited cell line would obviate the basis of this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand rejected under 35 U.S.C. 102(a) as being anticipated by Makino *et al.*

Initially, it is noted that the rejection with Makino *et al.* was made under 35 USC 102(a) not 102(b) as indicated by Applicants. See Applicants amendment, page 17. No other arguments are provided, except for the note that “can differentiate” has been amended to be “capable of differentiating”. See Applicants’ amendment, page 17. The rejection is maintained for the reasons of record.

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Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 stand are rejected under 35 U.S.C. 102(b) as being anticipated by Shi *et al.*

Applicants note that “can differentiate” has been amended to be “capable of differentiating”, and argue that the amendment overcomes the rejection. See Applicants’ amendment, page 17. Applicants arguments have been fully considered, but not found persuasive.

Examiner would acknowledge that Shi *et al.* does not specifically teach CD117 positive and CD140 positive adult stem cell. What appears to be at issue is the interpretation of the scope of the claims, in particular where CD117 positive and CD140 positive stem cells are found. The terms “can differentiate” and “capable of differentiating” are effectively equivalent. In interpreting the scope of the claims, in particular what type of cell(s) are encompassed Examiner has assessed the possible source of the cells encompassed by the claim in view of the teachings of the present specification. The present specification teaches that cells that are “CD117 positive and CD140 positive include mouse marrow multipotential stem cells (BMSC)” (page 27, lines 1-4). Further, it is noted that the claims to appear to encompass multiple cell types, since dependent claims set forth a variety of other cell surface markers, as well as other differentiating capacities. Again, Examiner would acknowledge that Shi *et al.* does not specifically teach CD117 positive and CD140 positive adult stem cell, however Shi *et al.* teach bone marrow stem cells and provides evidence that the cells are capable of differentiating into at least endothelial cells providing a functional property encompassed by the instant claims (claim 6-vascular endothelial cell).

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Again it is noted that where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 rejected under 35 U.S.C. 102(b) as being anticipated by Klug *et al.* is withdrawn.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 rejected under 35 U.S.C. 102(b) as being anticipated by Juttermann *et al.* is withdrawn.

Applicants note the amendment to the claims to encompass an "adult stem cell", and noting that embryonic stem cells are taught by Klug *et al.* and Juttermann *et al.* argue that such cells as provided by Klug *et al.* and Juttermann *et al.* are materially different. See Applicants' amendment, page 18.

Claims 1, 6-19, 21-28, 38, 39, 41, 43 and 44 rejected under 35 U.S.C. 102(a) as being anticipated by Young *et al.* is withdrawn.

The post filing evidence provided in the Young *et al.* references (see IDS filed May 16, 2006) demonstrates that the cells in the Young *et al.* reference used in the basis of the rejection fail to have the properties reasoned to be inherently present by the Examiner. More specifically, the cells isolated from muscle fail to be CD117 positive.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

Joe Voitach
AUG 32